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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/020,596	**Applicant(s)** BECKER, MICHAEL M.	
	Examiner Bradley L. Sisson	**Art Unit** 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See attached statement.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 1-25,27-32,34-36 and 61.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached statement.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: Statement attached.

Bradley L. Sisson
Primary Examiner
Art Unit: 1634

Objection to Specification

1. At page 10 of the response received 02 February 2005, and which was originally submitted on 24 January 2005, applicant's representative assert that the objection to the specification as it relates to the incorporation by reference should be withdrawn. Applicant's representative directs attention to MPEP 608.01(p) at 600-82, and asserts "that there is no obligation to point to the relevant portions of a document when an applicant believes, and the context suggests, that the referenced document as a whole is relevant."

2. As an initial matter, it is noted with particularity that the paragraph found at page 1, lines 14-22, which contained language stipulating that all cited documents had been incorporated by reference, was deleted via the amendment of 26 August 2004. In its place, applicant amended the disclosure and in so doing effectively deemphasized numerous documents and overemphasized others by selecting particular passages found in the specification where specific articles are not identified as "the contents of each of which is hereby incorporated by reference herein;" see the amendment to page 1, lines 14-22; paragraph bridging pages 5 and 6; paragraph bridging pages 7 and 8; paragraph bridging pages 11 and 12; paragraph bridging pages 20 and 21; paragraph bridging pages 23 and 24; page 27, lines 11-12; page 35, lines 9-23; paragraph bridging pages 35 and 36; paragraph bridging pages 37 and 38; and paragraph appearing at page 40, lines 4-18.

3. It is further noted that the newly added language of the amendment of 24 January 2005 does not stipulate if the documents are incorporated in their entireties, or in part, and if in part, which part is to be considered incorporated by reference.

4. The above argument has been fully considered and has not been found persuasive. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth In *Ex parte* Raible, 8 USPQ2d 1707, (BPAI, 1998)

> The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree
>
> * * *
>
> We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky , 474 F.2d 671, 177 USPQ 144 , (CCPA 1973).

5. To the extent that the specification contains reference to documents not indicated as being incorporated by reference, such cannot be relied upon for satisfaction of the written description or best mode requirements of 35 USC 112, first paragraph. Further, material found therein and which is essential to practicing the claimed invention cannot be brought forward into the instant application. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See*

> *General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application). (Emphasis added.)

6. Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

7. At page 11 of the response argument is advanced that the objection to the specification as it relates to the introduction of new matter should be withdrawn as the material was found within a document that had been incorporated by reference.

8. The above argument has been fully considered and ahs not been found persuasive for as shown above, the objection to the specification as it relates to the incorporation by reference of material has been maintained.

9. The Office acknowledges the amendment to the specification whereby an international application is now re-identified.

10. The objection to the specification as it relates to the change of "positive" to "negative" at page 4, line 16, of the original specification is withdrawn.

Claim Objections

11. The objection to claim 36 is withdrawn as a result of the amendment to same.

Rejection under 35 USC 112, first paragraph

12. At page 13 of the response of 24 January 2005 argument is advanced that "The Examiner has failed to state why the detection of multiple target nucleic acids would raise a written description issue since the stated objective of the claims is to detect nucleic acid.

13. Argument is also advanced that there is no explanation as to what an 'infinite' set of targets would be comprised of and how this potentially infinite set of target nucleic acids would wind-up in the sample being interrogated.

14. Argument is also advanced that "the rejection fails to take into consideration all of the limitations of the claim, as the claim specifically recites that the probe will 'preferentially hybridize' to the target nucleic acid, thereby indicating the presence of a specific target nucleic acid sequence." Attention is directed to specification at page 13, line 3 *et seq.*

15. For convenience, claim 1 is reproduced below.

1. (Previously Presented) A method for determining the presence of a target nucleic acid in a sample, said method comprising:

a) providing to a sample a negatively charged polynucleotide probe and a synthetic, water soluble polycationic polymer, wherein said probe is provided to said sample under conditions permitting said probe to preferentially hybridize to a target nucleic acid, which may be present in said sample, thereby forming a probe:target duplex, and wherein said polymer is provided to said sample in an amount sufficient to increase the association rate of said probe and said target nucleic acid in said sample under said conditions;

b) exposing said sample to a dissociating reagent in an amount sufficient to dissociate said polymer from said duplex after said probe and said target nucleic acid have had sufficient time to associate in said sample; and

c) determining whether said duplex is present in said sample as an indication of the presence or absence of said target nucleic acid.

16. As presently worded, the claimed method fairly encompasses the simultaneous detection of an infinite number of target sequences wherein the multitude of target nucleic acid sequences each have a different nucleotide composition. Said method also fairly encompasses situations where the quantity of one target sequence over that of another may range over several log phases. Further, the claimed method encompasses using the same label, or in fact no label.

17. In the event that multiple targets are to be detected simultaneously, there need be some mechanism to discriminate between one target and another. As presently worded, there is no means by which one would be able to determine with any degree of confidence if a given target, or targets are present, irrespective of one using conditions that permit "preferential hybridization." The claimed method is to result in the determination of the presence of a target nucleic acid. If multiple targets are to be detected simultaneously, and there is no means by which to discriminate one from another, then there is no reproducible means by which to detect "a" target nucleic acid in the multitude.

18. While attention has been directed to the definition of "preferentially hybridize," close inspection finds that the definition is not limiting. While agreement is reached that the specification states at page 13:

> By "preferentially hybridize" is meant that under the specified hybridization assay conditions, polynucleotide probes can hybridize to their target nucleic acids to form stable probe:target hybrids indicating the presence of a specific target nucleic acid sequence, and there is not formed a sufficient number of stable probe:non-target hybrids to indicate the presence of non-target nucleic acids. Thus, the probe hybridizes to target nucleic acid to a

It is noted that there is to be a difference between probe:target and probe:non-target complexes. Such differences, however, are subject to interpretation for a seen further on page 13:

> Preferably, there is at least a 10-fold difference between target and non-target hybridization signals in a test sample, more preferably at least a 100-fold difference, and most preferably at least a 1,000-fold difference. Preferably, non-target hybridization signals in a test sample are no more than the background signal level.

19. In view of the foregoing statements, the differences between the target and non-target hybridization signals have been construed as ranging from less than 10-fold to beyond 100-fold. In short, the difference between the respective hybridization signals can be virtually any value, so long as they are not the same.

20. As noted above, the claims have been construed as encompassing the simultaneous detection of multiple sequences, including target sequences that may be present in different quantities, wherein said differences can be 10-fold or 100-fold. In such situations, there is no reproducible means disclosed whereby the skilled artisan would be able to determine the presence of any given target nucleic acid as a target and non-target hybridization signals are indistinguishable.

21. At page 13 of the response of 24 January 2005 Applicant's representative asserts: "Applicant is unaware, however, of any obligation to provide examples to satisfy the written description requirement..."

22. While agreement is reached in that there is no *per se* rule that an application must contain examples, the specification must teach with such full, clear, and concise language the claimed invention so as to reasonably suggest that applicant was in possession of he invention at the time of filing. In support of this position attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

23. In the present case, the claims are all drawn to a method for determining the presence of a target nucleic acid. A review of the disclosure finds but two examples; Example 1, pages 42-48, and Example 2, page 49. As seen in Example 1, six different polymers were tested:

- poly-L-lysine hydrobromide with a molecular weight of from 20,000 to 30,000 Da
- poly-L-lysine hydrobromide with a molecular weight of from 150,000 to 300,000 Da
- poly (lys, tyr) 4:1, with an indicted molecular weight of 24,600 Da (visible)
- poly-L-histidine hydrochloride with an indicted molecular weight of 15,800 Da (using low angle laser light scattering)
- poly-L-arginine hydrochloride with an indicated molecular weight of 11,800 (visible)

- Hexadimethrine bromide

24. None of the examples teach the use of any cation, be it poly' or otherwise, other than the oligopeptides described above.

25. The specification does, however, point to a known problem associated with the use of polycations in hybridization reactions. As set forth at page 28:

> Polycationic polymers are known to significantly increase the T_m of nucleic acid duplexes, and large increases in T_m are often associated with a loss in discrimination.

And at page 29 of the specification a further cautionary note is provided:

> For detection assays, in which polynucleotide probes are intended to preferentially hybridize to target nucleic acid in the presence of non-target nucleic acid, the probes must be specific for the target nucleic acid in order for the assay to be of diagnostic or probative value. A loss in discrimination cannot be tolerated.

26. In accordance with claims 3-6, the polymer:

a. Is a copolymer;

b. Is a graft copolymer;

c. Has a delocalized charge;

d. Has a concentration in the range of about 10 μM to about 100 μM; and

e. Has a weight average molecular weight [*sic*] of less than about 300,000 Da.

While page 31, penultimate paragraph, does provide a listing of "contemplated" polycationic polymers, the specification does not provide an adequate written description of how these various polymers are to be used such that any target, or combination of targets can be determined. Such limited description dos not reasonably suggest that applicant was in possession of the full genus of methodologies, and the requisite starting materials, so to allow of

the practicing of the full scope of the claimed invention. In support of this position attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.
>
> ***
>
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

27. It is noted with particularity that applicant's assert at page 31:

> While not specifically enumerated, other polycationic polymers are envisaged by the present invention which function to enhance the association kinetics of complementary polynucleotides. Such polycationic polymers can be easily screened for by skilled artisans following the guidance provided herein without having to engage in anything more than routine experimentation.

Rather than provide the requisite full, clear, and concise description of the claimed invention, it appears that applicant is relying upon obviousness to satisfy the written description requirement. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

28. Furthermore, the specification fails to teach the detection of one nucleic acid over that of another, highly related sequence, e.g., a sequence that has a single point mutation. Also, the specification fails to teach how the claimed method is to be practiced when a virtually infinite number of polynucleotides are to be detected in a simultaneous manner when no label is used.

29. As presently worded, the reactants only need to be exposed to a "dissociation reagent in an amount sufficient to dissociate said polymer from said duplex." For purposes of examination, the "dissociation reagent" ha been construed as encompassing the hybridization buffer, water, or any other reactant that, when heated to various conditions, would result in said dissociation. It is further noted that while the claims stipulate that there needs to be a sufficient "amount," it does not have to be under conditions that would result in said dissociation, nor does the claim require that any dissociation actually take place.

30. At page 15 of the response applicant's representative directs attention to where various labels are disclosed in the specification.

31. The foregoing argument has been fully considered and has not been found persuasive towards the withdrawal of the rejections as limitations found in the specification are not read into the claims.

32. At page 15, penultimate paragraph, Applicant's representative directs attention to page 35, line 24 *et seq*, as to alternative assay formats, noting that the documents cited therein "are all incorporated by reference in their entireties."

33. The foregoing argument has not been found persuasive towards the withdrawal of the rejection for as discussed above, the cited documents have not been properly incorporated by reference and a such cannot now be relied upon for satisfaction of the requirements of 35 USC 112, first paragraph.

34. At page 15, bridging to page 16 of the response, argument is advanced that the term "duplex" has been misconstrued by the Office to encompass both duplex and triplex structures, but that Applicant's definition "provides that a 'duplex' is a stable nucleic acid structure comprising a double-stranded, hydrogen-bonded region." (Emphasis in the original.)

35. The above argument has been fully considered and has not been found persuasive as the very definition provided by applicant contains the term "comprises," which allows for the inclusion of additional elements, even in significant amounts so long as the basic characteristics are not altered. Further, there is no showing by applicant that a triplex structure does not comprise a duplex structure. Accordingly, the definition used by the Office is deemed reasonable and is therefore maintained.

36. To the extent that the claims have been rejected over interpretation of the phrase "in an amount sufficient to increase he association of said probe and said target nucleic acid," said rejection has been withdrawn in view of applicant's representative's remarks as found at page 16 of the response of 24 January 2005.

37. At page 16, bridging to page 17 of the response of 24 January 2005 Applicant's representative request clarification as to why an enablement issue exists even if the claims do encompass both organic and inorganic polycationic polymers exhibiting a range in hydrophobicity and hydrophilicity, and having virtually any upper mass.

38. It is noted with particularity that claims 1, 8-16, 21-25, 27-36 and 61 place no restriction on the type of polymer used in the assay. Accordingly, the claims have been interpreted as encompassing the use of virtually any polycationic polymer. Page 27 of the specification, however, teaches that rather than any polycationic polymer will function in the claimed assay, that the polycationic polymers must be screened.

> Through routine screening, the applicant also discovered that polycationic polymers can be selected which allow for some mismatch tolerance so that closely related strains of an organism or virus, for example, can be detected in an assay. These polymers

The specification further states, and cautions the skilled artisan that:

> Polycationic polymers are known to significantly increase the T_m of nucleic acid duplexes, and large increases in T_m are often associated with a loss in discrimination.

In view of this explicit caution, and the limited disclosure provided, and the broad breadth of scope of the claims currently before the Office, the specification does not fully enable the practicing of the claimed method, of the claimed method is not directed to screening of such polycationic polymers, but rather, the use of same in a specific method.

39. At page 17 of the response argument is again advanced over the interpretation of the hybridization conditions and the meaning ascribed to "preferentially hybridize." This argument

has been fully considered and has not been found persuasive towards the withdrawal of the rejection. See paragraphs 15-20, *supra*.

40. Upon consideration of applicant's arguments found at page 18 of the response, the rejection of claims 1-25, 27-32, 34-36, and 61 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention, is hereby withdrawn.

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

42. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

43. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
23 February 2005